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The Transatlantic Agbiotech Conflict as a Problem and Opportunity for EU Regulatory Policies

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1. Introduction: explaining the transatlantic conflict

The US and EU have developed quite different frameworks for agbiotech regulation, but these were potentially compatible with transatlantic trade in GM products. How, then, did a trade conflict arise? And why is it a problem?

Since the early 1990s the US government policy has treated agbiotech as technological progress yielding beneficial products which warrant no special label, and whose safety can be readily demonstrated through 'sound science'. Federal agencies readily approved or deregulated GM crops for cultivation and other uses. Food regulators routinely accepted company claims that GM foods had substantial equivalence with a safe counterpart, as grounds not to require safety approval.

By contrast the EU system has based its regulatory system on uncertainty about risks. By enacting the 1990 Deliberate Release Directive, the EU required a risk assessment and safety approval for all GM products. From 1996-97 the EU began to approve some GM products already commercialised in the US. And the EU eventually required statutory labelling, which became successively more stringent.

After public protest mounted in the late 1990s, the EU regulatory procedure underwent delays and blockages. In 1999 the EU Council suspended the decision-making procedure for new GM products, and some member states banned GM products which had already gained EU-wide approval. A trade conflict with the USA led to anticipation and threats of a WTO case, which was launched in 2003.

Trans-Atlantic regulatory divergence has been widely seen as the main source of the US-EU trade conflict. Moreover, each jurisdiction has been stereotyped in ways which diagnose why the divergence is a problem. According to some commentators, for example, the US bases its regulation on 'sound science', while EU restrictions and delays have accommodated the fears of an irrational public. According to other commentators, the US government bases safety claims on scientific ignorance and force-feeds the world with GM food, while the EU defends precaution and democratic sovereignty. Although these arguments differ greatly in standpoint, they all emphasise transatlantic differences and consequent problems.

This chapter challenges such explanations centering on transatlantic regulatory divergence. Instead it will ask: How did the trade conflict arise from policy agendas which span the Atlantic? How has it been framed as a problem and used as an opportunity for policy agendas within the EU? (For analogous roles within US policy debate, see Murphy and Levidow, 2006).

The rest of this Introduction summarises the overall argument, as follows: The US-EU conflict arose from contending transatlantic agendas, which have operated within and across the two jurisdictions. Corresponding to each agenda, trans-Atlantic coalitions framed the policy problem in three different ways: first, regulatory harmonisation for trade liberalisation of a benign technology and its safe products; second, the consumer right to know and choose safe food, based on precautionary risk assessment; and third, civil society participation in broad evaluation criteria for agbiotech products, which need prior proof of their safety.

The trade-liberalisation agenda set the context in which European protest could frame agbiotech as a dual threat of 'globalisation' and unknown risks. Greater controversy led to regulatory blockages

and a trade conflict, which policy actors diagnosed in ways convenient for their own agendas. Promoting agbiotech, some politicians warned that EU regulatory delays or more stringent rules would be found illegal at the WTO. But this strategy backfired; instead it provided a vulnerable target for attack by 'anti-globalisation' activists. Citing US threats of a WTO case, opponents sought to delegitimise pro-agbiotech policies as a surrender to political and commercial pressures.

From the late 1990s onwards, some European policymakers articulated a new problem – how 'to restore public and market confidence' – as an imperative for institutional reform. This problem-diagnosis helped to bypass earlier disagreements about the 'scientific' basis of regulatory criteria, thus facilitating more precautionary approaches to risk assessment and GM labelling. These changes accommodated key aspects of the 'consumer rights' agenda, thus potentially establishing a stronger basis to legitimise EU decisions.

As the conclusion will explain, the overall analysis extends insights from other academic accounts (Bernauer, 2003; Jasanoff, 2005; Toke, 2004; Isaac, 2002). This chapter also disagrees with some accounts, especially those which attribute the US-EU conflict to distinct jurisdictional characteristics. That analysis draws upon the results of three research projects [note 1].

As its structure, this chapter first sketches how contending transatlantic agendas generated the conflict. Then it shows how an EU regulatory impasse stimulated policy change in regulatory criteria and expert advisory arrangements. Finally the conclusion summarizes how contending transatlantic agendas operate within EU agbiotech regulation and drive its ongoing tensions.

2. Contending trans-Atlantic policy agendas

A trade-liberalisation agenda set the context in which European protest could frame agbiotech as a dual threat of 'globalisation' and unknown risks. Conflicts arose in the mid-1990s, especially around proposals to approve GM crops for cultivation, potentially leading to a US-EU trade conflict. This section describes how various policy actors used the conflict to elaborate and promote their contending agendas.

Using the transatlantic conflict: Bt maize crisis

As the EU statutory framework for agbiotech, the 1990 EC Deliberate Release Directive encompassed diverse agendas. It aimed to harmonise regulatory criteria for GM products, as a means 'to complete the internal market'. From this perspective, the policy problem was divergent national criteria which could impede internal trade. The solution lay in an EU-wide regulatory framework basing the internal market on a high level of protection for human health and the environment (EEC, 1990). By the mid-1990s those aims were linked with another policy framework: to promote agbiotech for European economic competitiveness (Levidow et al., 1996). These various agendas soon collided in decisions about specific GM products.

In late 1996 the EU Council members could not agree on whether to approve Ciba-Geigy's Bt-176 maize, present in grain shipments imminently arriving from the USA. The European Commission had the authority to make the decision itself, but its members could not agree, according to leaked minutes. The Trade Commissioner Leon Brittan argued that indecision in Brussels might anger the US government. Other Commissioners successfully advocated waiting for the opinions of three EU-level scientific committees, given the wider expert disagreements over safety. There were also disagreements about whether commercial approval should include a labelling requirement. Along with Leon Brittan, the Industry Commissioner Martin Bangemann opposed mandatory labelling; they argued that such a requirement might be illegal under international trade rules and could draw the EU into a trade dispute at the WTO (Rich, 1997: 8).

Meanwhile the mass media highlighted expert disagreements over product safety. Some experts were concerned that the antibiotic-resistance gene in the Bt-176 maize might enter pathogenic microbes and jeopardise the clinical use of the corresponding antibiotic. The Bureau Européen des Unions de Consommateurs (BEUC) emphasised several risks that had already been raised by some member states as a basis to oppose approval. But eventually the EU's expert bodies rejected all safety

concerns about the product. On those grounds, the European Commission approved Ciba-Geigy's Bt-176 maize in January 1997, despite opposition from nearly all EU member states..

The decision was widely attacked as illegitimate, especially by analogy to the 1996 BSE crisis. When the European Commission's minutes were leaked in the Belgian newspaper *Le Soir*, it used the headline 'After mad cow, recidivism with transgenic maize' (Rich, 1997: 1). According to a Green Member of the European Parliament, 'Despite mad cow, they have learned nothing!' The Pesticides Action Network argued, 'This is crazy. They have started a gigantic experiment with us as the guinea pigs' (ibid: 8). In April 1997 the European Parliament voted overwhelmingly to denounce the European Commission for its approval decision.

According to the Commission minutes, US maize shipments had been creating a strong pressure on the European Union to approve Bt-176 maize as quickly as possible. Some Commissioners were anticipating a compensation claim from the US if they failed to authorise the product. However, the Consumer Affairs Commissioner, Emma Bonino, expressed regret that the approval decision was responding to economic pressures. She believed that the European Commission should reflect on consumer concerns and their desire for transparency. Mentioning the BSE crisis, Commissioner Neil Kinnock said that consumer confidence must be re-established; maize is widely used and GM maize would be difficult to identify in derived products (ibid.).

In all those ways, an incipient trade conflict was being used for contending policy agendas within the EU. Arguments to minimise regulatory delays and criteria came from Commissioner Brittan, who was already championing trade liberalisation, and from Bangemann, who was promoting agbiotech as an imperative for the EU's economic competitiveness. Now they framed the trade conflict as EU delinquency which would result in a guilty verdict at the WTO. By contrast, other Commissioners echoed public concerns about scientific uncertainty and consumer choice. Some politicians sought to bypass the conflict through official expert advice, yet this too became part of the risk controversy. Meanwhile environmental NGOs sought to delegitimise any product approval, thus increasing the pressure upon governments to delay or reject such a decision. These policy agendas roughly correspond to formal coalitions, as described next.

Contending trans-Atlantic policy agendas

Pressures for rapid EU approval came from a trade liberalisation agenda. In 1995 the Commission's New Transatlantic Agenda (NTA) identified 'barriers to transatlantic trade' as the main problem for EU and US policy makers. Representing multinational companies, the Transatlantic Business Dialogue (TABD) helped to define the NTA's aims and the overall policy agenda. Regulatory harmonisation was expressed with the slogan, 'Approved Once, Accepted Everywhere', at least at the transatlantic level, ideally leading to a New Transatlantic Marketplace. In 1998 the US and EU governments established the Transatlantic Economic Partnership (TEP), a quasi-technical government-business network, to help implement TABD proposals. The DG-Trade Commissioner Leon Brittan led the EU-wide promotion of the trade liberalisation policy (Murphy and Levidow, 2006).

For the agricultural biotechnology sector, TABD members identified pre-market safety assessment as the only regulatory issue. TABD emphasised the need for a common approach across the Atlantic, and ideally a centralised approval procedure, based on 'sound science'. Designed as a largely technical body, the TEP aimed to identify regulatory differences as a step towards overcoming them.

According to Grant Isaac (2002), the NTA-TEP and TABD have both sought multilateral integration, towards 'allowing decentralised markets to achieve efficient and optimal objectives', though with different strategies. In his view, the TABD seeks to identify and coordinate any divergent regulations which may impede trade, and thus to develop a common regulatory framework. By contrast, the TEP seeks to internalise traditionally non-market, social objectives into such a framework (ibid: 27). Regardless of any such differences in emphasis, they shared a common agenda: how to harmonise risk assessment for trade liberalisation.

Although EU regulation of agbiotech diverged from the US model, the EC Deliberate Release Directive was foreseen as a means towards trade liberalisation. From the start, EU agbiotech

regulation framed GM techniques as a novel process which warranted special risk-assessment procedures for all GM products. European Commission staff advocated this regulatory framework as a basis for harmonising EU-wide regulatory criteria (Levidow et al., 1996), even for overcoming trans-Atlantic differences (Jasanoff, 2005: 82).

In the mid-1990s civil society protests began to challenge the neoliberal ‘free trade’ agenda, through movements widely called ‘anti-capitalist’ or ‘anti-globalisation’. Such protests created the context in which mainstream NGOs could more effectively challenge the NTA-TEP. Among other critics, consumer groups attacked the NTA-TEP for favouring industry influence and for ‘levelling down’ standards. Anti-agbiotech activists linked several threats: trade liberalisation policies, economic globalisation, corporate power and unknown risks of GM products.

Facing legitimacy problems, in 1998 the US and EU invited NGOs to establish their own ‘transatlantic dialogues’, as a basis to participate in the NTA-TEP process. Each network devised a different strategic response to that general process and to agbiotech in particular. Through the Transatlantic Consumer Dialogue (TACD), consumer NGOs found shared goals in ‘consumer rights’, such as the ‘right to safe products’, the ‘right to know and right to choose’, and jurisdictional sovereignty to accommodate diverse standards from consumer demands. They demanded precautionary regulation and full labelling of GM food products. Relative to TACD members, environmental groups were more antagonistic towards transatlantic trade liberalisation and agbiotech. The Transatlantic Environmental Dialogue (TAED) opposed agbiotech as long as there was no convincing evidence about its ‘harmlessness to man and nature’. They proposed civil society participation in broad evaluation criteria for agbiotech products. They also opposed the concentration of corporate control over the food system (Murphy and Levidow, 2006).

Thus agbiotech was framed in three different ways, corresponding to the three transatlantic Dialogues. Proponents linked the technology to efficient agriculture, economic growth, and benefits to farmers and the environment. Mainstream consumer groups did not oppose biotechnology in principle but demanded stronger regulatory frameworks from a consumer rights perspective. Especially in Europe, environmental groups framed the technology as an ominous symbol of corporate domination, economic globalisation and unsustainable agriculture.

From NGOs and some governments, critical voices gained a greater hearing in the EU policy system as intense public controversy erupted over agbiotech in the late 1990s. Protests coincided with a wider crisis of the agri-food safety system. The ‘mad cow’ epidemic was framed as a threat of intensive agriculture generating health hazards which elude the available scientific knowledge and official expert advice. According to some critics, intensive agriculture threatened alternative values and futures of European agriculture (Levidow and Marris, 2001). GM products were likewise turned into a symbol of such threats; EU democratic sovereignty was counterposed to ‘globalisation’ and the TABD-TEP agenda. Thus the US-EU agbiotech conflict arose from contending policy agendas operating across Atlantic.

3 Regulatory impasse as stimulus

In the late 1990s EU-wide regulatory conflicts challenged the narrow criteria which had facilitated product approvals. Beyond the Bt maize mentioned above, in 1997-98 the Commission granted EU-wide approval to some GM crops as normal commercial products, i.e. with no requirement for special control measures. Such decisions provoked dissent from member states and became targets for anti-agbiotech critics, e.g. on grounds that relevant uncertainties were ignored (Levidow et al., 2000).

Citing the familiar ‘pesticide treadmill’ as an analogy, agbiotech critics warned that GM crops would create a ‘genetic treadmill’, whereby weed or insect pests develop resistance to newly inserted genes. This resistance could pose a problem not only for pest control but also for additional pesticide sprays to control resistant pests. This scenario became a salient issue for GM herbicide-tolerant oilseed rape, which France prohibited in 1997. The debate there was used to generate resources for risk research; French scientists tested how far herbicide-tolerance genes flowed and persisted over several generations. The empirical results were cited to justify the original rationale for the French ban.

Potential harm to farmland biodiversity became a salient issue in the UK. Controversy focused on whether broad-spectrum herbicide sprays on GM herbicide-tolerant crops would cause relatively more or less harm to farmland biodiversity than their conventional counterparts. The government funded Farm-Scale Evaluations to obtain empirical evidence, whereby credible test methods depended upon involvement of a broader agro-environmental expertise, including nature conservation agencies. More generally, the UK government sought stronger empirical evidence to support official expert claims. Sceptical voices were encouraged to contribute to the UK policy debate, towards building a stronger consensus for agricultural biotechnology. In practice ‘this effort to broaden politics led to a more extensive unpacking of scientific unknowns’, argues Jasanoff (2005: 277).

By the late 1990s public protest was deterring approvals and a market for GM products. European supermarket chains decided to find alternative sources of grain, as a means to exclude GM ingredients from their own-brand products (Levidow and Bijman, 2002). Governments had greater difficulty to justify why they were continuing to support the commercial use of GM crops and foods. Some member states banned GM products that had already gained EU-level approval. Amid a legitimacy crisis and trade conflict, civil society organisations found greater opportunities to block agbiotech and/or to demand more stringent regulatory criteria. In such ways, they used the trade conflict to intensify domestic political conflict (cf. Bernauer, 2003).

In June 1999 some Ministers in the EU’s Environment Council agreed to block the regulatory procedure for GM products. Many of them signed one of two similar statements that they would not consider additional GM products for approval until the EU had made significant changes to its regulatory framework in order to address various weaknesses. To justify this delay, they cited ‘the need to restore public and market confidence’, while leaving ambiguous the object of lost confidence, e.g. GM products, EU regulatory procedures, etc.

Together those statements became known as an unofficial *de facto* moratorium on any further approvals of GM products. In their June 1999 statements, EU Environment Council members specified the regulatory changes necessary before the approvals procedure could resume. The list included: basing risk assessment upon precaution, and requiring traceability and labelling of all GM products and derived products. The European Commission still had the legal authority to approve products if the European Council failed to do so, but the Commission had a weaker will and political authority after the 1997 crisis over Ciba-Geigy’s Bt maize.

Stimulated by the *de facto* moratorium in 1999, the Commission initiated legislative changes to accommodate demands from member states. Until then, draft revisions of the Directive had aimed to streamline the approval procedure, potentially reducing regulatory burdens. After 1999 the redrafts incorporated more precautionary and stringent criteria (Levidow and Carr, 2000). For example, no risk should be ignored on grounds that it would be unlikely, and uncertainties should be explained for any identified risk (EC, 2001). Such rules formalised pressures to open up expert judgements about scientific uncertainty.

A common rationale for the *de facto* moratorium, the aim to ‘restore public and market confidence’, provided a means to go beyond previous disagreements about the ‘scientific’ basis for regulatory requirements. Institutional reforms provided a more flexible basis for regulatory-expert procedures to accommodate many concerns of mainstream consumer NGOs and environmental conservation groups – though not demands to prove ‘harmlessness’, which would have the effect of simply blocking GM products. These changes accommodated demands from many civil society organisations, while potentially creating a more legitimate basis to approve some GM products in the future.

4 Precautionary shifts in agbiotech regulation

Since the late 1990s conflicts continued over exactly how to revise and implement EU regulations. Meanwhile the US intensified its threats to bring a WTO case against the EU regarding agbiotech products. The Commission privately warned US officials that their overt threats were undermining its own efforts to establish a workable regulatory system.

Indeed, agbiotech critics used the transatlantic conflict to press for more stringent EU rules. The Commission generally favoured less-restrictive criteria than some member states did, especially on grounds that EU rules must be workable and comply with international commitments. Yet critics denounced its specific proposals as a surrender to US pressures, while advocating more stringent rules as necessary for EU sovereignty. When the European Parliament supported such rules on GM labelling, a Green MEP declared, 'It's a great victory for consumer choice and a clear message to Tony Blair and his American friends' (Agence Europe, 2002). After the US decision to launch a WTO case against the EU in May 2003, agbiotech critics likewise framed any EU approval of a GM product as a surrender.

In response the Commission has sought to counter public suspicions about external pressures. Eventually it promoted the new EU procedures as a better global model, whose credibility would depend upon timely implementation. In particular, member states should restart the procedure for approving GM products: 'We have to start because we want to demonstrate to the rest of the world that our way of taking decisions about GMOs works. Otherwise they will not believe us', according to the DG-Environment Commissioner (Margot Wallström, Associated Press, 28.01.04). After much effort along those lines, the Commission finally approved the first new GM product in spring 2004, the implementation date for new EU rules on traceability and labelling. Not coincidentally, this decision came just before a crucial meeting of parties to the WTO dispute.

Commission policy statements awkwardly combine diverse aims. For example: 'science-based regulatory oversight' aims 'to enable Community business to exploit the potential of biotechnology while taking account of the precautionary principle and addressing ethical and social concerns' (CEC, 2003: 6, 17). Shifts in practical meaning are summarised in Table 1: regulatory criteria in the left-hand side are sketched in this section, and expert advisory roles on the right-hand side are sketched in the subsequent section.

[insert Table 1 here]

Crop cultivation: agro-environmental risks

When GM crops were being evaluated for cultivation uses in the mid-1990s under the Deliberate Release Directive, sharp disagreements arose even before public debate became widespread. Proponents narrowly defined the 'adverse effects' to be evaluated, thus accepting the normal hazards of intensive monoculture. Environmental NGOs had warned that such products would result in a 'genetic treadmill', by analogy to the familiar 'pesticide treadmill'. Safety claims accepted such effects, e.g. the prospect of spreading herbicide-resistant weeds or insecticide-resistant insects; thus regulatory procedures accepted the inherent hazards of intensive monoculture.

This approach conceptually homogenised the European environment as a resource for efficient agri-production, as in the US model of intensive monoculture. Product approval decisions minimised responsibility for any undesirable effects. This approach facilitated EU-wide regulatory harmonisation, trans-Atlantic trade in GM products and thus the TABD-TEP agenda.

When the Directive was revised along more stringent lines, the revision broadened the range of agro-environmental effects which are to be prevented or managed; these included the effects of any changes in management practices, e.g. herbicide sprays. Market-stage monitoring could be required to verify any assumptions in the risk assessment (EC, 2001). Overall these changes broadened the scope of 'scientific' issues and of the European 'environment', thus complicating the earlier basis for regulatory harmonisation.

Another crisis provided an opportunity for different policy agendas. In the 2000 Starlink scandal, a GM maize had been legally cultivated by US farmers before government approval for food & feed purposes; such approval was ultimately denied because of doubts about health risks. Starlink maize was then found to be illegally present in the food chain, especially in North America but also in Europe. Anti-agbiotech groups cited this scandal to demand a ban on all GM products.

Yet the Commission used the scandal for a different agenda. Under the slogan, ‘one door, one key’, the Commission had been attempting to integrate approval for all product uses within ‘vertical’ product-based legislation since the mid-1990s. This proposal now gained support as a means to avoid another Starlink scandal, by ensuring that no GM crop cultivation would be authorised before approval for food and feed purposes.

In using this opportunity for legislative change, the Commission centralised the regulatory procedure. Under a new GM Food & Feed Regulation, advice from the European Food Safety Authority (see later section) would inform decisions by the Commission, coordinated and prepared by DG-Agriculture. Thus decisions to approve a GM crop for cultivation were removed from the Deliberate Release Directive, thus potentially bypassing the national authorities responsible for environmental protection. This change was widely criticised for marginalising environmental issues but prevailed in the final version (EC, 2003a). Parliament supported centralisation as a means to avoid the disagreements which had delayed regulatory decisions since the late 1990s.

GM food risks

When the EU was approving the first GM crops for cultivation, their food uses came under a new regime which facilitated approval decisions. The 1997 Novel Food Regulation had a simplified procedure for approving novel products including GM foods. A national authority need not carry out a risk assessment for any GM which had ‘substantial equivalence’ with a non-GM counterpart regarded as safe (EC, 1997a). In practice this procedure assumed that physico-chemical composition tests alone could demonstrate such equivalence. Under a similar policy, the US FDA did not generally require a risk assessment or even approval of GM foods. Complementing the TABD-TEP agenda, the EU simplified procedure facilitated regulatory harmonisation, thus helping to avoid trade barriers within the EU and across the Atlantic.

However, the concept of substantial equivalence underwent widespread criticism, especially as an ‘unscientific’ means to bypass risk assessment and safety tests. Some national expert advisory bodies were already interpreting the concept according to more stringent criteria; for example, they requested more rigorous evidence of physico-chemical composition, as well as more toxicological tests. Scientists’ efforts along those lines converged with demands of consumer organisations criticising substantial equivalence (Levidow et al., 2007).

Eventually substantial equivalence lost its statutory role. When Italy banned GM foods which had been approved by the US and EU, other member states joined its attack on the simplified procedure. Recognising its legitimacy problem, the Commission abandoned the simplified procedure when drafting the GM Food & Feed Regulation in 2001. Substantial equivalence would be kept as a risk-assessment tool, but EU-wide harmonisation might be difficult to achieve for this ‘dynamic concept’, whose interpretation was still under development, according to a Commission official (Pettau, 2002: 23). The concept of substantial equivalence continued to inform expert judgements in more stringent ways, as regards what evidence would be adequate for a risk assessment.

GM labelling and traceability

GM labelling rules have been introduced and extended to manage market instabilities. EU policy initially rejected demands that GM food should have a mandatory label. According to Commission officials, such a rule would stigmatise GM products as abnormal, threaten the internal market, and undermine science-based regulation. In response to public protest and consumer concerns, in 1997 the retail trade imposed its own labelling rules; these effectively defined what is/not a GM food, though the criteria varied across EU member states. Combined with public unease, diverse labelling criteria could have jeopardised the overall market for soya or maize, as well as the EU internal market. Recognising this problem, in 1997 new EU rules required labelling according to the detectability of DNA or protein at a 1% level.

Further changes in labelling rules were linked with market functions. As an extra condition for lifting the 1999 *de facto* moratorium, EU member states had demanded full labelling and traceability of GM ingredients, i.e. regardless of their detectability. In response, in 2001 the Commission issued draft legislation along those lines. Some Commissioners had previously opposed such rules but now

supported them as essential ‘for the free market to function effectively’. The new regime would allow a low threshold for ‘adventitious presence’ of GM material, i.e. levels which were technically unavoidable (EC, 2003a). Each GM crop must be traceable throughout the agro-food chain, e.g. by using ‘unique identifiers’ for the specific transformation event which constructed a GM crop (EC, 2003b). Retailers became dependent upon a paper trail to verify sources of grain, especially in cases where it is highly processed and so makes the DNA undetectable.

The new rules implicitly linked precaution with markets. Authorities could now trace and withdraw a product if problems arise later. Consumers would have a free, informed choice to avoid GM products and thus to make their own judgements on safety. Not simply ‘completing the internal market’, EU rules were redefining product-identity, thus restructuring markets for GM ingredients as well as non-GM food. In the original 1990 regulatory framework, the public had been cast as an audience for safety claims, as consumers of food potentially containing GM ingredients, and thus as supporters of a beneficial technology – roles which publics eventually rejected. New rules accommodated demands to extend consumer rights and to clarify the identity of any food which may contain GM ingredients. Using the new opportunity, anti-agbiotech activists sought to block GM grain whose products would now require a GM label under the new rules.

5. Expert authority for regulatory decisions

In parallel with the legislative changes sketched above, the EU also made changes in expert advisory arrangements (see Table 1, right-hand side). This meant more accountable ways of translating risk controversy and scientific uncertainty into criteria for evidence. These changes institutionalised aspects of the ‘consumer rights’ agenda, while incorporating consumer organisations into consultation procedures.

Precaution and uncertainty

In the late 1990s precaution was becoming more contentious as grounds to block products, especially in the agri-food sector. After the US brought its WTO case against the EU over hormone-treated beef, eventually the Appellate Body ruled that the defendant had failed to justify its beef ban through a risk assessment (WTO AB, 1998). Amid EU conflicts over the Precautionary Principle in many sectors, the Commission sought to clarify the concept.

According to its 2000 Communication, risk-management measures could be justified where uncertain risks jeopardise ‘the chosen level of protection’, i.e. the type or extent of risks deemed acceptable. In such cases, a risk assessment must demonstrate reasonable grounds to suspect that a product could cause ‘potentially dangerous effects’. Whenever taking precautionary measures, authorities must make efforts to obtain additional scientific information for ‘a more complete risk assessment’ (CEC, 2000).

The guidelines aimed to ensure that the Precautionary Principle would be used only in ways defensible under the EU’s treaty obligations. The Commission’s criteria were broader than in WTO rules and in some national policy frameworks, though more narrow than in some others. In effect, Commission guidelines provide a basis for selectively limiting the Precautionary Principle, i.e. to be invoked only in cases where the Commission decides to justify trade barriers. Such decisions would also depend upon expert bodies giving explicit advice about scientific uncertainty.

Advisory expertise

In the run-up to the BSE crisis, expert advice downplayed scientific uncertainties and made policy judgements about their manageability, yet safety claims were officially portrayed as ‘science’. Moreover, experts aimed to give advice that would be politically acceptable to regulators, while avoiding public alarm about any risks (Millstone and van Zwanenberg, 2001). The Commission likewise covered up the BSE problem, for fear that public concern about the BSE problem would endanger the European beef market, according to a report by the European Parliament (1997). Expert bodies were being used by politicians to avoid full responsibility for decisions. Consequently, EU safety claims came under greater suspicion as policy stances, especially given that expert

advisory bodies were hosted by the same Directorate-General responsible for relevant legislation and product approvals.

In response to various food crises including BSE, policymakers aimed to make EU scientific committees more independent in three respects: from DGs which propose and implement legislation, from member states, and from material interests. In reorganising its scientific committees, the Commission aimed 'to obtain timely and sound advice', 'based on the principles of excellence, independence and transparency' (EC, 1997b). Prospective members nominated themselves, rather than being chosen by member states. Risk assessment was separated from risk management through new arrangements, later described as a 'functional separation'. Scientific committees were shifted to the directorate-general for Consumer Health, renamed DG-SANCO.

Greater political dependence upon expert advice meant more conflicting advice and difficulties for regulatory harmonisation. Some member states created independent agencies whose risk-assessment advice often questioned safety assumptions, even the expert advice from EU-level scientific committees. In this way, 'The legitimacy and the autonomy of the European Commission, and indeed its *rappports de force* with the EU member states, are thus being displaced to the arena of scientific expertise' (Dratwa, 2004: 13).

EU expert advice was further restructured, as a means for the Commission to enhance its political authority, while incorporating potential critics into new institutions. Under a 2002 food law, the European Food Safety Authority (EFSA) was created as an independent body which would help set 'science-based' standards for risk assessment. It would have greater expert resources, needed to clarify or reconcile disagreements across different expert bodies (EC, 2002). In establishing EFSA, its Management Board included representatives of industry and consumer NGOs as partners with shared understandings of policy problems, especially the need to gain public confidence (Smith et al., 2004).

EU expert advice on GM products

In the EU regulatory procedure for evaluating GM products, there was much conflict over the criteria in the mid- to late 1990s. According to the advice of EU scientific committees on each product, there was no evidence to indicate that the product would cause adverse effects. Such a wording left ambiguous the burden of evidence to demonstrate safety. Safety claims often depended upon normative judgements, e.g. by classifying some undesirable effects as merely agronomic and therefore irrelevant, or by advising on the management of such effects, or by favourably comparing any harm from a GM crop to the harm from agrochemical usage. All these judgements came under criticism from member states (Levidow et al., 2000).

EFSA was established in 2003, when member states were again evaluating GM products under the revised Deliberate Release Directive. In evaluating a series of GM products, e.g. food or grain imports for feed, EFSA's Scientific Panel declared that each one would be as safe as its non-GM counterpart. Some safety claims still depended on normative judgements about acceptable effects.

Partly for those reasons, member states have often disagreed with EFSA's safety claims. Some have questioned whether the available information was adequate for a risk assessment, whether the environmental assessment adequately covered their specific conditions, and whether specific undesirable effects should be regarded as acceptable. Such criticisms were often taken up by other member states. These expert disagreements can be interpreted as different accounts of precaution, whereby safety claims correspond to more narrow accounts than objections; the latter define harm and uncertainty in broader ways (Levidow et al., 2005). In response to demands from some national regulators and NGOs, eventually the guidance notes asked all applicants for a 'risk characterisation', which would make scientific uncertainties more explicit (EFSA GMO Panel, 2004). In sum, expert advisory arrangements institutionalised aspects of the 'consumer rights' agenda, e.g. greater precaution and transparency, while incorporating consumer organisations into consultation procedures; these changes providing a stronger basis to legitimise safety claims and regulatory decisions.

6. Conclusion: contending policy agendas

Let us return to the questions posed in the Introduction: How did the US-EU conflict arise from contending agendas which span the Atlantic? How has the trade conflict been framed as a problem and used as an opportunity within the EU? Through those questions, this Conclusion discusses other major academic accounts of policy conflict over agbiotech.

As this essay has shown, the US-EU conflict arose from contending transatlantic agendas, which operated within and across the two jurisdictions. The policy problem was framed in three different ways, corresponding to the three Transatlantic Dialogues: regulatory harmonisation for trade liberalisation of a benign technology (TABD-TEP); the consumer right to know and choose safe food, based on precautionary risk assessment, with sovereignty to accommodate such criteria (TACD); and opposition to products lacking proof of safety and imposing corporate control over the agri-food chain (TAED). Thus a neoliberal policy agenda set the context in which European protest could frame agbiotech as a dual threat of 'globalisation' and unknown risks.

Jurisdictional characteristics and/or interactions?

Some academic analyses have attributed the US-EU conflict to separate jurisdictional characteristics. For example, US-EU differences in scientific risk assessment 'are related to different cultural attitudes' towards agbiotech, argues Toke (2004). According to Grant Isaac, 'endogenous political-economy factors' shape regulatory regimes in each jurisdiction, e.g. in the USA and EU (Isaac, 2002: 251). He emphasises their internal sources, 'because the domestic regulatory approach sets the prospects of and limits to regulatory integration' at the international level, e.g. through treaties (ibid: 24-25).

Of course these jurisdictional characteristics matter, but not as independent variables; at most they can explain internal conflicts and the relative strengths of contending transatlantic agendas within each jurisdiction. As EU domestic controversy and regulatory blockages led to a transatlantic trade conflict, policy actors diagnosed this as a problem according to their own agendas. The anti-agbiotech environmentalist agenda gained much greater support in Europe (than in the USA), e.g. by linking GM food with public suspicion towards hazards of intensive agriculture and undemocratic 'globalisation'. Amid a legitimacy crisis for government, civil society organisations found greater opportunities to block agbiotech and/or to demand more stringent regulatory criteria. In such ways, they used the trade conflict to intensify domestic political conflict (cf. Bernauer, 2003). The legitimacy problems and processes of European integration provided greater opportunity for those advocating more stringent rules or regulatory delays.

From the late 1990s onwards, some policymakers and expert advisors articulated a new problem – how 'to restore public and market confidence' – as an imperative for institutional reform. Eventually the EU enacted more precautionary legislation. It also established EFSA as a means to enhance the public credibility of expert advice, partly by incorporating consumer organisations into new structures. As regards market confidence, new labelling rules redefined 'GM food' in successively broader ways. Taking advantage of these more comprehensive rules, agbiotech opponents sought to extend the commercial blockage of GM grain.

The above story differs from some academic diagnoses of regulatory frameworks as a problem. According to David Toke (2004), national policies claim a scientific basis which in turn reinforces a given policy. Distinctive regulatory discourses are translated by scientists or expert advisors into 'factual' terms. A government may need to accommodate public concerns which eventually arise, so it would be better to anticipate them in advance. Yet an institutional path dependency often makes a policy framework insensitive or inflexible to such changes in context, he argues (ibid: 205-8). In his diagnosis, 'science-based regulation' readily becomes a constraint on policymaking. On the contrary, however, European expert advice flexibly changed its judgements along more stringent lines, thus stimulating and accommodating changes in regulatory policy, in response to public protest.

Going beyond an EU-US comparative approach, Thomas Bernauer (2003) analyses how transatlantic interactions underlie US-EU regulatory polarisation. Policy agendas have been driven by interest

groups seeking political and market influence, he argues. The trade conflict amplified domestic controversies over agbiotech. Civil society groups have used the trade conflict to press for higher regulatory standards, though more successfully in the EU than in the USA. Thus a trade liberalisation agenda stimulated a ‘trading up’ process, as theorised more generally by David Vogel (1995).

Perhaps unlike Vogel, and certainly unlike Toke, however, Bernauer diagnoses EU regulatory changes as a policy problem: Ever more complex, stringent, costly regulations are insufficiently backed by robust institutional structures for implementing them; overall the trade conflict may reduce investment in agri-biotechnology. As a remedy, more centralised forms of governance in food safety would increase consumer confidence, he argues (Bernauer, 2003). Yet all those changes and difficulties are inseparable elements of the overall story in this chapter: more stringent regulations remain crucial for accommodating the consumer rights frame, integrating its representatives within new structures, and thus potentially legitimising a centralised procedure.

Economic-scientific versus social rationalities?

As a general framework for analysing regulatory-trade conflicts, Grant Isaac argues that all regulations have two main functions. Their economic function is to improve the efficiency of the market system, while their social function is to ensure that market activity takes place in a way consistent with the preferences and expectations within a jurisdiction. These functions frame policy issues in different ways:

[The] economic perspective generally assumes that technology and innovation are vital factors of economic growth and welfare. As a result, it supports a regulatory framework that encourages technological progress. For instance, it is quite common for economic analysis to support ‘scientific-rationality’ approaches to regulating the risk of new technology... The economic- and scientific-rationality perspectives are similar, in that they decompose complex behaviour and actions into causal-consequence models, which are then used to forecast outcomes (Isaac, 2002: 16-17).

[The] ‘social-rationality’ approach holds that it is insufficient to view new technology and innovations simply as a positive force in economic growth. Instead, the social implications of science must be considered and, under this consideration, new technology may not always be greeted without reservation – despite its potential to improve economic growth (ibid: 21).

To develop a stable regulatory framework, a jurisdiction must find some way to ‘balance’ scientific and social rationality. In his view, ‘the ideal regulatory framework essentially builds social credence into the scientific-rationality paradigm’. In particular, such a framework would acknowledge that normative issues are prior to empirical ones, so that science can help risk regulation to address societal concerns, argues Isaac (ibid: 257). While acknowledging normative issues, he diagnoses an imbalance or separation between social and scientific-economic rationality, thus implying that they could remain separate.

On the contrary, the EU story here illustrates how such rationalities were always linked, in changing ways. As an explicit means ‘to restore public and market confidence’, EU reforms changed the previous relation between social, scientific and economic criteria. ‘Science-based regulation’ now depended upon different social norms than before, e.g. as regards the wider potential effects and uncertainties to be evaluated. Efficient ‘free markets’ now depended upon a clearer product-identity through GM labelling rules, lest ambiguity undermine food markets. These changes can build social credence into scientific rationality, while expressing public preferences through social rationality (cf. Isaac, 2002).

In this case, however, any such rationality remains within the limits of a product safety framework. EU advisory expertise was restructured as a means to strengthen safety claims, to enhance the Commission’s political authority, to promote regulatory harmonisation and to keep any precautionary measures compatible with EU treaty obligations. When more transparent uncertainties and stringent criteria are cited to justify approvals of GM products, such decisions can accommodate the ‘consumer rights’ frame – separated from the wider issues of the anti-agbiotech frame and demands for alternative agricultures. In this way, recent institutional reforms may help politicians to justify EU regulatory approval decisions which avoid trade barriers, thus facilitating trade liberalisation.

However, legitimacy problems continue as the EU relegates societal decisions to product safety and markets. According to Commission policy, risk regulation ‘is the expression of societal choices’: rules should ensure that market mechanisms function effectively, so that safe products are available to accommodate consumer preferences (CEC, 2002: 14). The EU policy problem can be diagnosed as a pervasive tension between the three contending agendas – especially between trade liberalisation versus democratic sovereignty over societal futures, beyond simply regulatory criteria for safe products.

What European integration?

What does this mean for the shape and legitimacy of European integration? Sheila Jasanoff analyses biotech in such terms. As biotech innovation devised novel ‘designs on nature’, its governance challenged some founding assumptions of liberal democracy, e.g. ‘that citizens have the capacity to participate meaningfully in decisions that seem increasingly to call for specialized knowledge and expertise’. Through various expert bodies, democratic control over biotech ‘was sometimes set aside in favor of other culturally sanctioned notions about what makes the exercise of power legitimate’ (Jasanoff, 2005: 272, 287). Within the EU agenda of regulatory harmonisation, agbiotech regulation undergoes a tension between two political models: seeking to eliminate national divergences in policy framings, versus protecting deep-seated national values that generate them (ibid: 71).

The EU story in this chapter suggests more complex, contradictory futures. Whenever one member state proposes more stringent criteria or broader framings for risk assessment, such proposals have often gained support from others, as a potential European standard (Levidow et al., 2005). Possible futures go beyond simply maintaining national differences within the EU or else harmonising them away. Consequently, regulatory harmonisation remains a dynamic process of disputing, broadening and levelling up standards. In its own way, EU agbiotech regulation shapes the future European Union and its basis for democratic legitimacy.

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 - ‘Precautionary Expertise for GM Crops (PEG)’, funded by the European Commission, DG-Research, Quality of Life programme, during 2002-04. Reports available at <http://technology.open.ac.uk/cts/peg/index.html>
 - ‘Trading Up Environmental Standards? Transatlantic Governance of GM Crops’, funded by the UK’s Economic and Social Research Council between 2002-04. Brochure available at <http://technology.open.ac.uk/cts/bpg/index.html>; also book (Murphy and Levidow, 2006).

Table 1: Policy Changes in EU Agbiotech Regulation

	agbiotech risk legislation	GM food regulation	GM labelling & consumer choice	scientific uncertainty: policy role	EU advisory expertise: general arrangements	EU expert advice on GM products
mid-90s	DRD bases the internal market on high level of envtl & health protection; harmonise criteria	substantial equivalence can justify GM food safety	no GM labelling should be required for safe products	safety based on 'sound science'; no evidence of risk (uncertainty ignored)	hosted by the Directorate-General responsible for legislation and product approvals	[no EU-level expert advice on GM products]
post-BSE crisis (1996-97)	proposals to streamline DRD procedures and to lighten regulatory burdens	NFR bases the simplified procedure on substantial equivalence	GM food must be labelled according to scientific criteria of detectability	debate over how expert procedures should address uncertainty about risks	establish advice independent of policy influence, material interests & member states	'no evidence of risk' from each GM product; 'adverse effects' are defined narrowly
late 1990s	broaden risk asst and require market-stage monitoring (2001 revision of DRD)	some member states imposed more stringent criteria for 'substantial equivalence'	GM labelling rules are extended to additives	guidelines for triggering the Precautionary Principle, i.e. measures to manage uncertain risks	functionally separate risk asst from risk mgt, thus protecting the scientific integrity of expert advice	no reason to indicate that (each) GM product will cause adverse effects
Since 2001	centralise expert advice to facilitate harmonisation (GM F&F Regn)	abandon the simplified procedure for GM food (GM F&F Regn)	label food according to any GM source and ensure traceability (T&L Regn)	any restriction must be justified by a risk assessment indicating uncertain risks	EFSA to clarify different views of expert bodies, and to build expert networks (2002 food law)	safety claims undergo pressures to acknowledge uncertainties and normative judgements
Explicit policy aims	exploit the potential of biotechnology while taking account of the precautionary principle and social concerns	substantial equivalence remains a 'dynamic concept' for assessing GM food safety	free choice to buy GM or non-GM food; ensure that the free market can function	PP must be used in ways compatible with EU treaty obligations	independent, objective advice should inform decisions which can gain public confidence	obtain adequate data to clarify uncertainties and overcome expert disagreements in risk asst

Abbreviations

DRD = Deliberate Release Directive (EEC, 1990; EC, 2001)

EFSA = European Food Safety Authority (EC, 2002)

GM F&F = GM Food & Feed Regulation (EC, 2003a)

NFR = Novel Food Regulation (EC, 1997a)

PP = Precautionary Principle (e.g. CEC, 2000)

T&L = Traceability and Labelling Regulation (EC, 2003b)

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